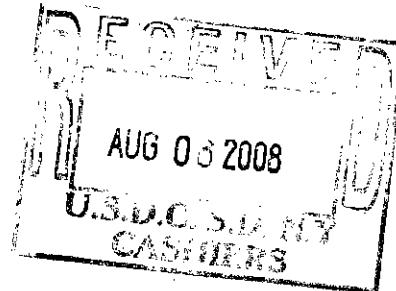


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 and Takeda Global Research and Development Center, Inc.  
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**UNITED STATES DISTRICT COURT  
 SOUTHERN DISTRICT OF NEW YORK**

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Takeda Pharmaceutical Company Limited,  
 Takeda Pharmaceuticals North America, Inc.,  
 and Takeda Global Research and Development  
 Center, Inc.,

Civil Action No. \_\_\_\_\_

Plaintiffs,

v.

Mylan, Inc.,  
 Mylan Pharmaceuticals, Inc., and  
 UDL Laboratories, Inc.

**COMPLAINT**

Defendants.

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Plaintiffs, Takeda Pharmaceutical Company, Limited (formerly known as Takeda Chemical Industries, Ltd.) ("TPC"), Takeda Pharmaceuticals North America, Inc. ("TPNA"), and Takeda Global Research & Development Center, Inc. ("Takeda Global") (collectively, "Takeda") by their undersigned counsel, for their Complaint against defendants Mylan Pharmaceuticals, Inc. ("MPI"), Mylan, Inc. ("Mylan, Inc."), and UDL Laboratories, Inc. ("UDL") (collectively "Mylan"), allege as follows:

**Jurisdiction and Venue**

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code and arising under 35 U.S.C. §§ 271(e)(2), 271(b), 271(c) and 281-283. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper under 28 U.S.C. §§ 1391(b)-(c) and 1400(b). Personal jurisdiction over the defendants in New York is proper under N.Y. C.P.L.R. §§ 301 and 302(a) and because defendants are doing business in this jurisdiction.

**Parties**

2. TPC is a Japanese corporation having its corporate headquarters in Osaka, Japan and principal place of business in Osaka, Japan. TPNA is a wholly owned U.S. subsidiary of Takeda American Holdings, Inc., which is a wholly owned U.S. subsidiary of TPC. TPNA has its corporate headquarters and principal place of business in Deerfield, Illinois and is organized under the laws of Delaware. Takeda Global is a wholly owned subsidiary of TPNA. Takeda Global has its corporate headquarters and principal place of business in Deerfield, Illinois, and is organized under the laws of Delaware.

3. TPC is engaged in the business of research, developing, manufacturing, and marketing of a broad spectrum of innovative pharmaceutical products, including ACTOPLUS MET®, which comprises a combination of the active ingredients pioglitazone hydrochloride and metformin hydrochloride.

4. Upon information and belief, MPI is incorporated in West Virginia and has a place of business in Morgantown, West Virginia. Upon information and belief, Abbreviated New Drug Application (“ANDA”) No. 90-406 was filed under the name of MPI.

5. Upon information and belief, defendant Mylan, Inc. is a Pennsylvania corporation having its corporate headquarters in Canonsburg, Pennsylvania. Upon information and belief, Mylan, Inc. has actual control over the activities of MPI which is a wholly owned subsidiary of Mylan, Inc.

6. Upon information and belief, UDL is an Illinois corporation having its principal place of business in Rockford, Illinois. UDL supplies, markets, sells and distributes pharmaceuticals to all fifty states, including at least New York. Upon information and belief, Mylan has actual control over the activities of UDL which is a wholly owned subsidiary of Mylan, Inc.

7. Upon information and belief, Mylan is currently transacting business in the Southern District of New York, at least by making and shipping into this Judicial District, or by using, offering to sell or selling or by causing others to use, offer to sell or sell, pharmaceutical products. Mylan derives substantial revenue from interstate and/or international commerce, including substantial revenue from goods used or consumed or services rendered in the State of New York and the Southern District of New York. MPI is registered with the N.Y. State Department of State, Division of Corporations, to do business as a foreign corporation in New York. Additionally, Mylan, Inc. common stock is listed on the New York Stock Exchange and Mylan, Inc. has contractual dealings with at least the American Stock Transfer & Trust Company located at 59 Maiden Lane, Plaza Level, New York, NY 10038. By filing its ANDA, Mylan has committed, and unless enjoined, will continue to commit a tortious act without the state of New York, that Mylan expects or should reasonably expect to have consequences in the State of New York.

**The New Drug Application**

8. TPNA sells drug products containing a combination of pioglitazone hydrochloride and metformin hydrochloride under the trade name ACTOPLUS MET® in the United States pursuant to the United States Food and Drug Administration's ("FDA") approval of a New Drug Application ("NDA") held by Takeda Global (NDA No. 21-842).

9. ACTOPLUS MET® is approved for use as an adjunct to diet and exercise to improve glycemic control in patients with Type 2 Diabetes (non-insulin-dependent diabetes mellitus).

10. The approval letter for ACTOPLUS MET®, with approved labeling, was issued by the FDA on August 29, 2005.

**The Patents in Suit**

11. United States Patent No. 5,965,584 ("the '584 patent"), entitled "Pharmaceutical Composition," a true and correct copy of which is appended hereto as **Exhibit A**, was duly issued on October 12, 1999 to inventors Hitoshi Ikeda, Takashi Sohda and Hiroyuki Odaka and assigned to plaintiff TPC. The '584 patent claims, inter alia, a pharmaceutical composition comprising pioglitazone or salts thereof in combination with a biguanide (e.g., metformin) and methods for treating diabetes which comprise administering a therapeutically effective amount of pioglitazone or salts thereof in combination with a biguanide, such as metformin. Claim 13 recites that pioglitazone and biguanide are administered as an admixture. The '584 patent covers the drug approved in NDA No. 21-842.

12. Plaintiff TPC has been and still is the owner through assignment of the '584 patent, which expires on June 19, 2016.

13. United States Patent No. 6,166,043 ("the '043 patent"), entitled "Pharmaceutical Composition," a true and correct copy of which is appended hereto as **Exhibit B**, was duly issued on December 26, 2000 to inventors Hitoshi Ikeda, Takashi Sohda and Hiroyuki Odaka, and assigned to plaintiff TPC. The '043 patent claims, *inter alia*, methods for reducing the amount of active components administered to a diabetic patient, which comprise administering a therapeutically effective amount of pioglitazone or salts thereof in combination with a biguanide, such as metformin.

14. Plaintiff TPC has been and still is the owner through assignment of the '043 patent, which expires on June 19, 2016.

15. United States Patent No. 6,172,090 ("the '090 patent"), entitled "Pharmaceutical Composition," a true and correct copy of which is appended hereto as **Exhibit C**, was duly issued on January 9, 2001 to inventors Hitoshi Ikeda, Takashi Sohda and Hiroyuki Odaka, and assigned to plaintiff TPC. The '090 patent claims, *inter alia*, methods for reducing the side effects of active components administered to a diabetic patient, which comprise administering a therapeutically effective amount of pioglitazone or salts thereof in combination with a biguanide, such as metformin, as the active components.

16. Plaintiff TPC has been and still is the owner through assignment of the '090 patent, which expires on June 19, 2016.

17. Plaintiff TPC has granted an exclusive license to plaintiff TPNA under the '584 patent, the '043 patent, and the '090 patent (collectively, "Takeda Patents").

18. In accordance with its exclusive license, plaintiff TPNA sells drug products containing a combination of pioglitazone and metformin under the trade name ACTOPLUS

MET® in the United States. Sales of TPNA's drug products containing a combination of pioglitazone and metformin are made pursuant to approval by the FDA of NDA No. 21-842.

19. Plaintiff Takeda Global is the holder of NDA No. 21-842, under which TPNA sells ACTOPLUS MET®.

20. Plaintiff TPC manufactures the drug products containing a combination of pioglitazone and metformin, that are sold by TPNA.

21. Plaintiffs TPC, TPNA and Takeda Global will be both substantially and irreparably harmed by infringement of any of the Takeda Patents. There is no adequate remedy at law.

**COUNT I**

**(DIRECT INFRINGEMENT OF THE '584 PATENT UNDER  
35 U.S.C. § 271(e)(2)(A))**

22. Plaintiffs TPC, TPNA and Takeda Global repeat and incorporate herein by reference the allegations contained in paragraphs 1 through 21 above.

23. Upon information and belief, defendant MPI, under the control of defendant Mylan, Inc., filed an Abbreviated New Drug Application ("ANDA") with the FDA under 21 U.S.C. § 355(j) (ANDA No. 90-406) seeking approval to market (i) tablets comprising a combination of 15 mg/500 mg of pioglitazone hydrochloride/metformin hydrochloride, and (ii) tablets comprising a combination of 15 mg/850 mg of pioglitazone hydrochloride/metformin hydrochloride.

24. By this ANDA filing, Mylan has indicated that it intends to engage, and that there is substantial likelihood that it will engage, in the commercial manufacture, use, offer for sale, and/or sale of plaintiffs' patented pioglitazone/metformin drug products, immediately or

imminently upon receiving FDA approval to do so. Also by its ANDA filing, Mylan has indicated that its combination pioglitazone and metformin drug products are bioequivalent to Takeda's combination pioglitazone and metformin drug products.

25. By its ANDA filing, Mylan seeks to obtain approval to commercially manufacture, use, offer for sale and/or sell alleged generic equivalents of plaintiffs' ACTOPLUS MET® pioglitazone and metformin combination drug products prior to the expiration date of the '584 patent.

26. By a letter (the "Notice Letter") dated June 23, 2008, MPI informed plaintiffs that MPI had filed a certification to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). On or about June 24, 2008, NDA holder, Takeda Global, received the Notice Letter. On or about June 26, 2008, patent owner, TPC, received a duplicate original of the Notice Letter.

27. The Notice Letter, purporting to be MPI's Notification of Certification under 21 U.S.C. § 355(j)(2)(B)(iv), alleges that in Mylan's opinion, the '584 patent is "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the drug products described in Mylan's ANDA."

28. Mylan's filing of ANDA No. 90-406 for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale and/or sale (or the inducement thereof or contribution thereto) of drug products containing pioglitazone and metformin or salts thereof before the expiration of the '584 patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

29. Mylan's manufacture, use, offer for sale, and/or sale (or the inducement thereof or contribution thereto) of its proposed combination pioglitazone and metformin drug products will directly infringe at least one of the claims of the '584 patent.

30. Unless Mylan is enjoined from infringing, contributing to and/or inducing the infringement of the '584 patent, plaintiffs will suffer substantial and irreparable injury. Plaintiffs have no adequate remedy at law.

## COUNT II

### **(INDUCEMENT OF INFRINGEMENT OF METHOD CLAIMS OF THE '584 PATENT UNDER 35 U.S.C. § 271(b))**

31. Plaintiffs TPC, TPNA and Takeda Global repeat and incorporate herein by reference the allegations contained in paragraphs 1 through 30 above.

32. On information and belief, approval of ANDA 90-406 is substantially likely to result in the commercial use, manufacture, offer for sale and/or sale, or inducement thereof, of a drug product which is marketed and sold for use in a method claimed in one or more claims of the '584 patent, immediately or imminently upon approval of the ANDA.

33. Upon information and belief, Mylan is aware or reasonably should be aware, of the widespread use of pioglitazone in combination with metformin, for the treatment of Type 2 Diabetes.

34. Additionally, upon information and belief, Mylan's proposed label for its combination pioglitazone and metformin products will instruct patients to take pioglitazone in combination with metformin for the treatment of Type 2 Diabetes. The beneficial effects of such combination therapy are well known to Mylan and to customers of Mylan. Mylan will be marketing its pioglitazone and metformin combination drug products with specific intent, and/or with the desire, to actively induce, aid and abet infringement of the '584 patent. Mylan knows or reasonably should know that its proposed conduct will induce infringement of the '584 patent.

35. Upon information and belief, Mylan's generic marketing practices include listing generic products on its website and referring customers to a corresponding brand name product. Upon information and belief, Mylan intends to do the same for any approved generic pioglitazone and metformin combination drug product, namely Mylan intends to list its generic product and refer customers to Takeda's product, ACTOPLUS MET®. Upon information and belief, such marketing practices are substantially likely to lead a customer of a generic combination pioglitazone and metformin drug product to infer that prescribing information for ACTOPLUS MET®, which includes directions relating to the use of a combination of pioglitazone and metformin, also applies to Mylan's generic combination pioglitazone and metformin drug products.

36. Upon information and belief, the acts of infringement alleged above are and have been deliberate and willful.

37. Plaintiffs will be substantially and irreparably harmed if defendants are not enjoined from inducing the infringement of the '584 patent. Plaintiffs have no adequate remedy at law.

### **COUNT III**

#### **(CONTRIBUTORY INFRINGEMENT OF THE '584 PATENT UNDER 35 U.S.C. § 271(c))**

38. Plaintiffs TPC, TPNA and Takeda Global repeat and incorporate herein by reference the allegations contained in paragraphs 1 through 37 above.

39. On information and belief, Mylan seeks FDA approval of ANDA 90-406 exclusively for use in treating Type 2 Diabetes, and does not suggest any alternative use for its pioglitazone and metformin combination drug products.

40. Upon information and belief, approval of ANDA 90-406 is substantially likely to result in the commercial use, manufacture, offer for sale and/or sale (or the inducement thereof or contribution thereto) of a drug product which is especially made, adapted, marketed, sold, and approved exclusively for use in a method claimed in one or more claims of the '584 patent, immediately or imminently upon approval of the ANDA.

41. Upon information and belief, the acts of infringement alleged above are and have been deliberate and willful.

42. Plaintiffs will be substantially and irreparably harmed if defendants are not enjoined from contributing to the infringement of the '584 patent. Plaintiffs have no adequate remedy at law.

**COUNT IV**

**(DIRECT INFRINGEMENT OF THE '043 PATENT UNDER  
35 U.S.C. § 271(e)(2)(A))**

43. Plaintiffs TPC, TPNA and Takeda Global repeat and incorporate herein by reference the allegations contained in paragraphs 1 through 42 above.

44. Upon information and belief, defendant MPI, under the control of defendant Mylan, Inc., filed an ANDA with the FDA under 21 U.S.C. § 355(j) (ANDA No. 90-406) seeking approval to market (i) tablets comprising a combination of 15 mg/500 mg of pioglitazone hydrochloride/metformin hydrochloride, and (ii) tablets comprising a combination of 15 mg/850 mg of pioglitazone hydrochloride/metformin hydrochloride.

45. By this ANDA filing, Mylan has indicated that it intends to engage, and that there is substantial likelihood that it will engage, in the commercial manufacture, use, offer for sale, and/or sale of plaintiffs' patented pioglitazone/metformin drug products, immediately or

imminently upon receiving FDA approval to do so. Also by its ANDA filing, Mylan has indicated that its combination pioglitazone and metformin drug products are bioequivalent to Takeda's combination pioglitazone and metformin drug products.

46. By its ANDA filing, Mylan seeks to obtain approval to commercially manufacture, use, offer for sale and/or sell alleged generic equivalents of plaintiffs' ACTOPLUS MET® pioglitazone and metformin combination drug products prior to the expiration date of the '043 patent.

47. By a Notice Letter dated June 23, 2008, MPI informed plaintiffs that MPI had filed a certification to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). On or about June 24, 2008, NDA holder, Takeda Global, received the Notice Letter. On or about June 26, 2008, patent owner, TPC, received a duplicate original of the Notice Letter.

48. The Notice Letter, purporting to be MPI's Notification of Certification under 21 U.S.C. § 355(j)(2)(B)(iv), alleges that in Mylan's opinion, the '043 patent is "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the drug products described in Mylan's ANDA."

49. Mylan's filing of ANDA No. 90-406 for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale and/or sale (or the inducement thereof or contribution thereto) of drug products containing pioglitazone and metformin or salts thereof before the expiration of the '043 patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

50. Mylan's manufacture, use, offer for sale, and/or sale (or the inducement thereof, or contribution thereto) of its proposed combination pioglitazone and metformin drug products will directly infringe at least one of the claims of the '043 patent.

51. Unless Mylan is enjoined from infringing, contributing to and/or inducing the infringement of the '043 patent, plaintiffs will suffer substantial and irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT V**

**(INDUCEMENT OF INFRINGEMENT OF THE '043 PATENT  
UNDER 35 U.S.C. § 271(b))**

52. Plaintiffs TPC, TPNA and Takeda Global repeat and incorporate herein by reference the allegations contained in paragraphs 1 through 51 above.

53. On information and belief, approval of ANDA 90-406 is substantially likely to result in the commercial use, manufacture, offer for sale and/or sale, or inducement thereof, of a drug product which is marketed and sold for use in a method claimed in one or more claims of the '043 patent, immediately or imminently upon approval of the ANDA.

54. Upon information and belief, Mylan is aware or reasonably should be aware, of the widespread use of pioglitazone in combination with metformin, for the treatment of diabetes, and particularly to reduce the amount of active components administered to the diabetic patient.

55. Additionally, upon information and belief, Mylan's proposed label for its combination pioglitazone and metformin products will instruct patients to take pioglitazone in combination with metformin for the treatment of Type 2 Diabetes. The beneficial effects of such combination therapy are well known to Mylan and to customers of Mylan. Mylan will be marketing its pioglitazone and metformin combination drug products with specific intent, and/or with the desire, to actively induce, aid and abet infringement of the '043 patent. Mylan knows or reasonably should know that its proposed conduct will induce infringement of the '043 patent.

56. Upon information and belief, Mylan's generic marketing practices include listing generic products on its website and referring customers to a corresponding brand name product. Upon information and belief, Mylan intends to do the same for any approved generic pioglitazone and metformin combination drug product, namely Mylan intends to list its generic product and refer customers to Takeda's product, ACTOPLUS MET®. Upon information and belief, such marketing practices are substantially likely to lead a customer of a generic combination pioglitazone and metformin drug product to infer that prescribing information for ACTOPLUS MET®, which includes directions relating to the use of a combination of pioglitazone and metformin, also applies to Mylan's generic combination pioglitazone and metformin drug products.

57. Upon information and belief, the acts of infringement alleged above are and have been deliberate and willful.

58. Plaintiffs will be substantially and irreparably harmed if defendants are not enjoined from inducing the infringement of the '043 patent. Plaintiffs have no adequate remedy at law.

**COUNT VI**

**(CONTRIBUTORY INFRINGEMENT OF THE '043 PATENT  
UNDER 35 U.S.C. § 271(c))**

59. Plaintiffs TPC, TPNA and Takeda Global repeat and incorporate herein by reference the allegations contained in paragraphs 1 through 58 above.

60. On information and belief, Mylan seeks FDA approval of ANDA 90-406 exclusively for use in treating Type 2 Diabetes, and does not suggest any alternative use for its pioglitazone and metformin combination drug products.

61. On information and belief, approval of ANDA 90-406 is substantially likely to result in the commercial use, manufacture, offer for sale and/or sale (or the inducement thereof or contribution thereto) of a drug product which is especially made, adapted, marketed, sold, and approved exclusively for use in a method claimed in one or more claims of the '043 patent, immediately or imminently upon approval of the ANDA.

62. Upon information and belief, the acts of infringement alleged above are and have been deliberate and willful.

63. Plaintiffs will be substantially and irreparably harmed if defendants are not enjoined from contributing to the infringement of the '043 patent. Plaintiffs have no adequate remedy at law.

**COUNT VII**

**(DIRECT INFRINGEMENT OF THE '090 PATENT UNDER  
35 U.S.C. § 271(e)(2)(A))**

64. Plaintiffs TPC, TPNA and Takeda Global repeat and incorporate herein by reference the allegations contained in paragraphs 1 through 63 above.

65. Upon information and belief, defendant MPI, under the control of defendant Mylan, Inc., filed an ANDA with the FDA under 21 U.S.C. § 355(j) (ANDA No. 90-406) seeking approval to market (i) tablets comprising a combination of 15 mg/500 mg of pioglitazone hydrochloride/metformin hydrochloride, and (ii) tablets comprising a combination of 15 mg/850 mg of pioglitazone hydrochloride/metformin hydrochloride.

66. By this ANDA filing, Mylan has indicated that it intends to engage, and that there is substantial likelihood that it will engage, in the commercial manufacture, use, offer for sale, and/or sale of plaintiffs' patented pioglitazone/metformin drug products, immediately or

imminently upon receiving FDA approval to do so. Also by its ANDA filing, Mylan has indicated that its combination pioglitazone and metformin drug products are bioequivalent to Takeda's combination pioglitazone and metformin drug products.

67. By its ANDA filing, Mylan seeks to obtain approval to commercially manufacture, use, offer for sale and/or sell alleged generic equivalents of plaintiffs' ACTOPLUS MET® pioglitazone and metformin combination drug products prior to the expiration date of the '090 patent.

68. By a Notice Letter dated June 23, 2008, MPI informed plaintiffs that MPI had filed a certification to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). On or about June 24, 2008, NDA holder, Takeda Global, received the Notice Letter. On or about June 26, 2008, patent owner, TPC, received a duplicate original of the Notice Letter.

69. The Notice Letter, purporting to be MPI's Notification of Certification under 21 U.S.C. § 355(j)(2)(B)(iv), alleges that in Mylan's opinion, the '090 patent is "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the drug products described in Mylan's ANDA."

70. Mylan's filing of ANDA No. 90-406 for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale and/or sale (or the inducement thereof or contribution thereto) of drug products containing pioglitazone and metformin or salts thereof before the expiration of the '090 patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

71. Mylan's manufacture, use, offer for sale, and/or sale (or the inducement thereof or contribution thereto) of its proposed combination pioglitazone and metformin drug products will directly infringe at least one of the claims of the '090 patent.

72. Unless Mylan is enjoined from infringing, contributing to and/or inducing the infringement of the '090 patent, plaintiffs will suffer substantial and irreparable injury. Plaintiffs have no adequate remedy at law.

### **COUNT VIII**

#### **(INDUCEMENT OF INFRINGEMENT OF THE '090 PATENT UNDER 35 U.S.C. § 271(b))**

73. Plaintiffs TPC, TPNA and Takeda Global repeat and incorporate herein by reference the allegations contained in paragraphs 1 through 72 above.

74. On information and belief, approval of ANDA 90-406 is substantially likely to result in the commercial use, manufacture, offer for sale and/or sale, or inducement thereof, of a drug product which is marketed and sold for use in a method claimed in one or more claims of the '090 patent, immediately or imminently upon approval of the ANDA.

75. Upon information and belief, Mylan is aware or reasonably should be aware, of the widespread use of pioglitazone in combination with metformin, for the treatment of diabetes and particularly for reducing the side effects of active components administered to a diabetic patient.

76. Additionally, upon information and belief, Mylan's proposed label for its combination pioglitazone and metformin products will instruct patients to take pioglitazone in combination with metformin for the treatment of Type 2 Diabetes. The beneficial effects of such combination therapy are well known to Mylan and to customers of Mylan. Mylan will be marketing its pioglitazone and metformin combination drug products with specific intent, and/or with the desire, to actively induce, aid and abet infringement of the '090 patent. Mylan knows or reasonably should know that its proposed conduct will induce infringement of the '090 patent.

77. Upon information and belief, Mylan's generic marketing practices include listing generic products on its website and referring customers to a corresponding brand name product. Upon information and belief, Mylan intends to do the same for any approved generic pioglitazone and metformin combination drug product, namely Mylan intends to list its generic product and refer customers to Takeda's product, ACTOPLUS MET®. Upon information and belief, such marketing practices are substantially likely to lead a customer of a generic combination pioglitazone and metformin drug product to infer that prescribing information for ACTOPLUS MET®, which includes directions relating to the use of a combination of pioglitazone and metformin, also applies to Mylan's generic combination pioglitazone and metformin drug products.

78. Upon information and belief, the acts of infringement alleged above are and have been deliberate and willful.

79. Plaintiffs will be substantially and irreparably harmed if defendants are not enjoined from inducing the infringement of the '090 patent. Plaintiffs have no adequate remedy at law.

**COUNT IX**

**(CONTRIBUTORY INFRINGEMENT OF THE '090 PATENT  
UNDER 35 U.S.C. § 271(c))**

80. Plaintiffs TPC, TPNA and Takeda Global repeat and incorporate herein by reference the allegations contained in paragraphs 1 through 79 above.

81. On information and belief, Mylan seeks FDA approval of ANDA 90-406 exclusively for use in treating Type 2 Diabetes, and does not suggest any alternative use for its pioglitazone and metformin combination drug products.

82. On information and belief, approval of ANDA 90-406 is substantially likely to result in the commercial use, manufacture, offer for sale and/or sale (or the inducement thereof or contribution thereto) of a drug product which is especially made, adapted, marketed, sold, and approved exclusively for use in a method claimed in one or more claims of the '090 patent, immediately or imminently upon approval of the ANDA.

83. Upon information and belief, the acts of infringement alleged above are and have been deliberate and willful.

84. Plaintiffs will be substantially and irreparably harmed if defendants are not enjoined from contributing to the infringement of the '090 patent. Plaintiffs have no adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

(a) A declaratory judgment pursuant to 28 U.S.C. § 2201 et seq. that making, using, selling, offering to sell and/or importing Mylan's drug products for which it seeks FDA approval or the active ingredients pioglitazone and metformin in

- combination, and/or inducing or contributing to the same, will infringe at least one claim of the Takeda Patents;
- (b) A declaratory judgment pursuant to 28 U.S.C. § 2201 et seq. that inducing the making, using, offering for sale, selling and/or importing of Mylan's drug products or the active ingredients pioglitazone and metformin in combination, will infringe at least one claim of one or more of the Takeda Patents;
  - (c) A declaratory judgment pursuant to 28 U.S.C. § 2201 et seq. that contributing to the making, using, offering for sale, selling and/or importing of Mylan's drug products or the active ingredients pioglitazone and metformin in combination, will infringe at least one claim of one or more of the Takeda Patents;
  - (d) A declaratory judgment pursuant to 28 U.S.C. § 2201 et seq. and an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval for Mylan to commercially make, use, sell, offer to sell or import pioglitazone in combination with metformin or any drug product containing pioglitazone in combination with metformin be no earlier than the date following the expiration date of the last to expire of the '584 patent, the '043 patent, or the '090 patent;
  - (e) A permanent injunction restraining and enjoining against any infringement by defendants, their officers, agents, attorneys, or employees, or those acting in privity or concert with them, of the '584 patent, the '043 patent or the '090 patent through the commercial manufacture, use, sale, offer for sale or importation into the United States of pioglitazone or any drug product containing pioglitazone in

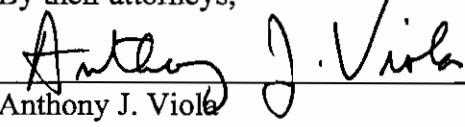
combination with metformin, and/or any inducement of and/or any contribution to the same;

- (f) Attorneys' fees in this action under 35 U.S.C. § 285;
- (g) Such further and other relief as this Court may deem just and proper.

Dated: New York, New York  
August 5, 2008

Takeda Pharmaceutical Company, Limited,  
Takeda Pharmaceuticals, North America, Inc. and  
Takeda Global Research & Development Center,  
Inc.

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